

Application Serial No. 10/047,578
Amendment dated February 23, 2004
Reply to Office Action dated December 23, 2003

Listing of Claims:

1. (Presently Amended) A composition comprising:

a plurality of the active pharmaceutical ingredients, said active pharmaceutical ingredients being phenylephrine and pyrilamine and being present as a plurality of dosage forms, each of said dosage forms including an amount of said active pharmaceutical ingredients, said amount being generally uniform in each of said dosage forms, when compared one to another, the composition formed from the steps of:

- a. dissolving active pharmaceutical ingredients consisting of phenylephrine and pyrilamine in a first solvent to form a first solution, wherein dissolving said active pharmaceutical ingredients under conditions that will not cause decomposition of the active pharmaceutical ingredients;
- b. mixing a dispersing agent and tannic acid in a second solvent to form a first dispersion;
- c. transferring at least a portion of the first solution to the first dispersion, to form a second solution including tannate salts of the active pharmaceutical ingredients;
- d. combining substances selected from the group consisting of preservatives, suspending agents, thickening agents, coloring agents, anti-caking agents, sweetening agents, flavoring agents and pH adjusting

Application Serial No. 10/047,578
Amendment dated February 23, 2004
Reply to Office Action dated December 23, 2003

- agents to form a liquid pharmaceutical carrier; and
- e. combining at least a portion of the second solution to the liquid pharmaceutical carrier to produce a liquid dosage form including pharmaceutically active tannate salts.
2. (Original) The composition of claim 1 wherein the active pharmaceutical ingredients are present in a range of about 0.05% to about 25.0% by weight.
3. (Original) The composition of claim 1 wherein the active pharmaceutical ingredients are selected from the group of salts consisting of maleate, citrate, chloride, bromide, acetate, and sulfate.
4. (Original) The composition of claim 1 wherein the tannic acid is natural or synthetic.
5. (Original) The composition of claim 1 wherein the dispersing agent is selected from the group consisting of magnesium aluminum silicate, xanthan gum and cellulose compounds.

Application Serial No. 10/047,578
Amendment dated February 23, 2004
Reply to Office Action dated December 23, 2003

6. (Original) The composition of claim 5 wherein the dispersing agent is magnesium aluminum silicate and is present in a range of about 0.05% to about 5.0% by weight.
7. (Original) The composition of claim 1 wherein the tannic acid is present in a range of about 0.05 to about 10.0% by weight.
8. (Original) The composition of claim 6 wherein the magnesium aluminum silicate and tannic acid are present by weight in a ratio in the range of 0.1:1 to 100:1.
9. (Original) The composition of claim 1 wherein the tannic acid and the active pharmaceutical ingredients are present by weight in a ratio in the range of 2:1 to 10:1.
10. (Original) The composition of claim 1 wherein the thickening agent is magnesium aluminum silicate and is present in a range of about 0.5% to about 10.0% by weight.
11. (Original) The composition of claim 1 wherein the suspending agent is kaolin and is present in a range of about 0.5 to about 10.0% by weight.

Application Serial No. 10/047,578
Amendment dated February 23, 2004
Reply to Office Action dated December 23, 2003

12. (Original) The composition of claim 1 wherein the sweetening agents include sucrose present in a range of about 5.0% to about 50.0% by weight, and saccharin sodium present in a range of about 0.01% to about 3.0% by weight.
13. (Original) The composition of claim 1 wherein the flavoring agent is artificial grape and is present in a range of about 0.01% to about 2.0% by weight.
14. (Original) The composition of claim 1 wherein the second solvent is water and is present in a range of about 10.0 to about 75.0% by weight.
15. (Original) The composition of claim 1 wherein said second solvent is glycerin and is present in a range of about 2.5% to about 20.0% by weight.
16. (Original) The composition of claim 1 wherein the preservative is methylparaben and is present in a range of about 0.01 to about 1.0% by weight.
17. (Original) The composition of claim 1 wherein the pH adjusting agent is benzoic acid and is present in a range of about 0.05 to about 1.0% by weight.
18. (Original) The composition of claim 1 wherein the anti-caking agent is pectin and is present in the range of about 0.5 to about 10.0% by weight.

Application Serial No. 10/047,578
Amendment dated February 23, 2004
Reply to Office Action dated December 23, 2003

19. (Original) The composition of claim 1 wherein the pH of said liquid dosage form is in a range of about 3.5 to 6.5.
20. (Original) The composition of claim 1 wherein the pharmaceutically active tannate salts are pyrilamine tannate present at about 30mg and phenylephrine tannate present at about 12.5mg.
21. (Original) The composition of claim 19 wherein said liquid dosage form is a suspension.
22. (Previously Canceled)
23. (Previously Canceled)
24. (Previously Canceled)
25. (Previously Canceled)
26. (Previously Canceled)

Application Serial No. 10/047,578
Amendment dated February 23, 2004
Reply to Office Action dated December 23, 2003

27. (Previously Canceled)

28. (Previously Canceled)

29. (Previously Canceled)

30. (Previously Canceled)

Application Serial No. 10/047,578
Amendment dated February 23, 2004
Reply to Office Action dated December 23, 2003

31. (Presently Amended) A composition comprising:

a plurality of active pharmaceutical ingredients, said active pharmaceutical ingredients being selected from the group consisting of phenylephrine and pyrilamine and being present as a plurality of dosage forms, each of said dosage forms including an amount of said active pharmaceutical ingredients, said amount being generally uniform in each of said dosage forms, when compared one to another, the composition formed from the steps of:

- a. dissolving active pharmaceutical ingredients consisting of phenylephrine and pyrilamine in a first solvent to form a first solution, wherein dissolving said active pharmaceutical ingredient occurs under conditions that will not cause decomposition of the active pharmaceutical ingredients;
- b. mixing a dispersing agent, diluent and tannic acid in a second solvent to form a first powder mixture;
- c. transferring at least a portion of the first solution to the first powder mixture, to form tannate salts of the active pharmaceutical ingredients in a second powder mixture;
- d. adding substances selected from the group consisting of dry binding/matrix forming agents and a binder solution to the second powder mixture in order to form a granulation;
- e. combining the granulation with substances selected from the group

Application Serial No. 10/047,578
Amendment dated February 23, 2004
Reply to Office Action dated December 23, 2003

- consisting of diluent, coloring agents, sweetening agents, hardness-increasing agents, flavoring agents, and excipients; and
- f. processing the granulation into solid dosage forms.
32. (Previously Amended) The composition of claim 31 wherein the active pharmaceutical ingredients are free bases or salts selected from the group consisting of maleate, citrate, chloride, hydrochloride, bromide, hydrobromide, acetate, sulfate, mesylate, palmitate, and stearate.
33. (Previously Amended) The composition of claim 31 wherein the tannic acid is natural or synthetic.
34. (Previously Amended) The composition of claim 31 wherein the dispersing agent is selected from the group consisting of magnesium aluminum silicate, xanthan gum and cellulose compounds.
35. (Previously Amended) The composition of claim 31 wherein the solvents are selected from the group consisting of purified water, ethanol, diethylether, methylene chloride, acetone, and isopropyl alcohol.

Application Serial No. 10/047,578
Amendment dated February 23, 2004
Reply to Office Action dated December 23, 2003

36. (Previously Amended) The composition of claim 31 wherein the diluent is selected from the group consisting of lactose, microcrystalline cellulose, sucrose and mannitol and is present in a concentration of about 1.0 to about 75.0%.
37. (Previously Amended) The composition of claim 31 wherein the binder solution comprises material selected from the group consisting of corn starch, pregelatinized starch, potato starch, polyvinylpyrrolidone and xanthan gum and is present in a concentration of about 0.1% to about 20.0%.
38. (Previously Amended) The composition of claim 37 wherein the binder solution further comprises a solvent.
39. (Previously Amended) The composition of claim 38 wherein the solvent is selected from the group consisting of purified water, ethanol, diethylether, methylene chloride, acetone, and isopropyl alcohol.
40. (Previously Amended) The composition of claim 31 wherein the dry binding/matrix forming agents are selected from the group consisting of methylcellulose, hydroxypropyl methyl cellulose, ethylcellulose, hydroxypropyl cellulose, xanthan gum and polyvinyl pyrrolidone and each is present at a concentration of about 0.1% to about 20.0%.

Application Serial No. 10/047,578
Amendment dated February 23, 2004
Reply to Office Action dated December 23, 2003

41. (Previously Amended) The composition of claim 31 wherein the coloring agents are selected from the group consisting of blue, red, yellow, green, orange, and purple and each is present at a concentration of about 0.01% to about 2.0%.
42. (Previously Amended) The composition of claim 31 wherein the sweetening agents are selected from the group consisting of sucrose, saccharin sodium, xylitol and sucralose and each is present at a concentration of about 0.01% to about 40.0%.
43. (Previously Amended) The composition of claim 31 wherein the flavoring agents are selected from grape, cherry, orange, lime and strawberry and is present in a concentration of about 0.01% to about 3.0%.
44. (Previously Amended) The composition of claim 31 wherein the dispersing agent is magnesium aluminum silicate and is present in about 0.05% to about 15.0% by weight.
45. (Previously Amended) The composition of claim 31 wherein the tannic acid is present in the range of about 0.05% to about 30.0% by weight.

Application Serial No. 10/047,578
Amendment dated February 23, 2004
Reply to Office Action dated December 23, 2003

46. (Previously Amended) The composition of claim 44 wherein the ratio of magnesium aluminum silicate to tannic acid is present in the weight ratio of 0.1:1 to 100:1.
47. (Previously Amended) The composition of claim 31 wherein the tannic acid and the active pharmaceutical ingredients are present in the weight ratio 2:1 to 10:1.
48. (Previously Amended) The composition of claim 31 wherein the tannate salts are pyrilamine tannate present at 30mg and phenylephrine tannate present at 25mg.
49. (Previously Canceled)
50. (Previously Canceled)
51. (Previously Canceled)
52. (Previously Canceled)

Application Serial No. 10/047,578
Amendment dated February 23, 2004
Reply to Office Action dated December 23, 2003

53. (Presently Amended) A composition comprising:

a plurality of active pharmaceutical ingredients, said active pharmaceutical ingredients being tannate salts and being present as a plurality of dosage forms, each of said dosage forms including an amount of said active pharmaceutical ingredients, said amount being generally uniform in each of said dosage forms, when compared one to another, the composition being formed by a method comprising:

- a. dissolving active pharmaceutical ingredients selected from the group consisting of phenylephrine and pyrilamine in a first solvent to form a first solution, wherein dissolving said active pharmaceutical ingredients occurs at a temperature and pH value that will not cause decomposition of the active pharmaceutical ingredients;
- b. mixing a dispersing agent and tannic acid in a second solvent to form a first dispersion; and
- c. transferring at least a portion of the first solution to the first dispersion, to form a second solution including tannate salts of the active pharmaceutical ingredients.